# Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>	
19/08/2002		☐ Protocol	
Registration date 19/08/2002	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	[] Individual participant data	
15/11/2019	Cancer		

**Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

LU16

# Study information

#### Scientific Title

Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

#### **Study objectives**

Not provided at time of registration.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Small-Cell Lung Cancer (SCLC)

#### **Interventions**

1. Oral Etoposide Regimen (E): Four courses of oral etopsimide twice daily for ten days at three week intervals (i.e. ten days of chemotherapy in each three week period).

#### 2. Intravenous Multi-Drug

Chemotherapy Regimen (EV or CAV): Clinicians chose to use one of two multi-drug chemotherapy regimens: EV: Intravenous etoposide and vincristine four courses given at three

week intervals, each course given over three days according to the protocol.

CAV: Intravenous cyclophosphamide, doxorubicin and vincristine four courses given at three week intervals, each course given on one day.

All treatments should start as soon as possible after randomisation.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Etopsimide, cyclophosphamide, doxorubicin and vincristine

#### Primary outcome measure

Not provided at time of registration.

#### Secondary outcome measures

Not provided at time of registration.

#### Overall study start date

01/08/2002

#### Completion date

01/08/2003

# **Eligibility**

#### Key inclusion criteria

- 1. Microscopically proven SCLC
- 2. Limited or extensive disease
- 3. World Health Organisation (WHO) performance status grade two, three or four
- 4. No previous chemotherapy, radiotherapy, or surgery for small-cell lung cancer
- 5. No other previous or concomitant malignant disease, except basal cell carcinoma or in situ carcinoma of the cervix
- 6. No other serious condition contraindicating treatment with cytotoxic chemotherapy. Patients with evidence of liver cell damage are eligible
- 7. Renal function normal: plasma creatinine or urea concentration within normal limits
- 8. Plasma Billirubin less than 35 µmol/l
- 9. Any age, either sex

#### Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Target number of participants

Not provided at time of registration.

#### Total final enrolment

339

#### Key exclusion criteria

Not provided at time of registration.

#### Date of first enrolment

01/08/2002

#### Date of final enrolment

01/08/2003

# Locations

# Countries of recruitment

England

United Kingdom

# Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

Medical Research Council (MRC) (UK)

## Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

#### Sponsor type

Research council

#### Website

# Funder(s)

# Funder type

Research council

#### **Funder Name**

Medical Research Council (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

#### Funding Body Type

Government organisation

## **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/08/1996	15/11/2019	Yes	No